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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,518	12/21/1998	YI LI	PF218US	9737

22195 7590 07/21/2003

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EXAMINER
PAK, MICHAEL D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/21/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/101,518	LI, YI	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-128* is/are pending in the application.

4a) Of the above claim(s) *33-50,56-63,65-73,79-96,102-109 and 111-119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-32, 51-55, 64, 74-78, 97-101, 110, 120-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1.5, 23* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *22* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Amendment filed 18 March 2003 (Paper No. 20) has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed 18 March 2003 (Paper No. 20), have been fully considered but they are not found persuasive.

Election/Restrictions

4. Applicants argue that Paper No. 17 of examiner's action presents no reason for the restriction of Groups 14-18 from Group 3.

The inventions listed as Groups 1-18 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of Group I is the polynucleotide. Pursuant to 37 CFR 1.475(d), these claims are considered by the ISA/US to constitute the main invention, and none of the related groups 2-13 correspond to the main invention. The original claim 1 of group I lacks the special technical feature because it is anticipated by the Marchesi et al. (Genomics, 1995) as recited in the search report of PCT/US96/00499.

The products of Groups 2-5 and 14-18 do not share the same or corresponding special technical feature with Group 1, because they are drawn to products having

materially different structures and functions, and each defines a separate invention over the art.

The methods of Groups 6-13, do not share the same or corresponding special technical feature with Group 1, because the methods have materially different process steps and are practiced for materially different purposes, and each defines a separate invention over the art.

Since Groups 1-18 do not share a special technical feature, unity of invention is lacking.

Applicants argue that under MPEP 1850 unity of invention is only considered for the independent claims and not the dependent claims. However, PCT rule 13.3 specifically state that the determination of unity of invention is not affected by manner of claiming the invention. Furthermore, claim 1 of group 1 lack the special technical feature and the products do not define a separate invention over the art.

Applicants argue that under 35 USC 121 that the examination of the Groups 14-18 would not present a serious burden. However, the search burden is not a specific issue under lack of unity practice. Even if consider the search burden, each of the groups 14-18 are classified separately in the US classification system.

Group 14, classified in class 530, subclass 387.5.

Group 15, classified in class 530, subclass 388.1.

Group 16, classified in class 530, subclass 389.1.

Group 17, classified in class 530, subclass 387.3.

Group 18, classified in class 435, subclass 334.

5. Newly submitted claims 124-126 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Group 15: Claim 124 and 126, drawn to an antibody which is monoclonal, classified in class 530, subclass 388.1.

Group 16: Claim 126, drawn to an antibody which is polyclonal, classified in class 530, subclass 389.1.

Group 17: Claim 125-126, drawn to an antibody which are chimeric, single chain, humanized, and human, classified in class 530, subclass 387.3.

The inventions listed as Groups 1-18 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of Group I is the polynucleotide. Pursuant to 37 CFR 1.475(d), these claims are considered by the ISA/US to constitute the main invention, and none of the related groups 2-13 correspond to the main invention. The original claim 1 of group I lacks the special technical feature because it is anticipated by the Marchesi et al. (Genomics, 1995) as recited in the search report of PCT/US96/00499.

The products of Groups 2-5 and 14-18 do not share the same or corresponding special technical feature with Group 1, because they are drawn to products having materially different structures and functions, and each defines a separate invention over the art.

The methods of Groups 6-13, do not share the same or corresponding special technical feature with Group 1, because the methods have materially different process steps and are practiced for materially different purposes, and each defines a separate invention over the art.

Since Groups 1-18 do not share a special technical feature, unity of invention is lacking.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 124-126 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Declaration

6. The Declaration of Melanie Lenhart under 37 CFR 1.132 filed 18 March 2002 is sufficient to to support the amendment of the sequence listing and amendment of the sequence errors in the specification.

Claim Rejections - 35 USC 101

7. Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to an isolated antibody which specifically binds the HSATU68 protein polypeptide comprising SEQ ID NO:2 or a fragment of the polypeptide where HSATU68 is a G-protein coupled receptor (GPCR) where GPCR is an orphan G-protein coupled receptor with no known ligand. The specification as filed does not disclose or provide evidence that points to a property of the claimed receptor such that another non-asserted utility would be well established. Since the function of the protein is not known because the ligand is not known, the protein lacks substantial and well established utility. The specification on pages 5 and 20 disclose the asserted utility of administering a compound to a host which bind to and inhibit activation of the receptor polypeptides of the present invention which are useful in the prevention and/or treatment of a list of diseases. However, there is no nexus between the unknown properties of the GPCR receptor polypeptide and the treatment of the list of diseases. The GPCR orphan receptor polypeptide does not have a substantial and well established utility because different receptors would have different functions and the skilled artisan would have to determine the function of the orphan receptor. The specification on pages 3-4 teaches that the family of chemokines exhibit a wide variety of functions and thus as group have been implicated in a number of physiological and disease conditions. However, the list of diseases are for various functions of different chemokines with different function some of which are to inhibit while others are to stimulate. The lack of knowledge of the ligand and the function of HSATU68 G-protein coupled receptor does not provide a substantial utility because without function a nexus to the function and disease does not exist. It should be noted that the utility of

chemokine is based on the assumption that HSATU68 is a chemokine receptor. The assumption is based on sequence identity with known chemokine receptors but until the ligand is identified the real identity of the receptor is guess work. Therefore, the invention is not in readily available form at the time of the invention. Thus, the study of GPCR lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Any utility of the antibody which bind the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The claimed antibody do not have substantial utility because the skilled artisan would need to prepare, isolate, and analyze the receptor protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. *Brenner V. Manson 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966)* stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search, but compensation for its successful conclusion."

Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim R j ctions - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 encompass the term "specifically bind" which is ambiguous and the metes and bounds are not clear because the it is a relative term. The degree of binding is determined by the binding conditions of the assay and metes and bounds of when something binds specifically cannot be determined without the binding assay limitations compared with the standard control non-specific binding assay.

Claims 75-78 encompass the term "HSATU68 polypeptide coding region" which is ambiguous because it is not clear what is the metes and bounds of the term. The term "HSATU68 polypeptide" does not provide a specific structure of the polypeptide and can encompass a fragment of two amino acids which is encoded by ATCC deposit 97334.

Claims 121-123 and 127-128 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are the ambiguity with the preamble term "recombinant HSATU68 protein expressed on cell surface" and the limitation a) which does not link a relationship between the polynucleotide and the recombinant HSATU68 polypeptide. Without the relationship between the polynucleotide and HSATU polypeptide, the claims encompass any HSATU68 polypeptide which is not defined by structure or function.

9. Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 encompass antibody which binds peptide variants and fragments of HSATU68 polypeptide which is an orphan G-protein receptor. However, the essential feature of the invention is the peptide of SEQ ID NO:2, and one of skilled in the art cannot envision the full genus of antibodies which bind claimed variant molecules. The claims encompass antibody which bind variants whose structure is not known or other variant proteins with different function from SEQ ID NO:2 taught in the specification because the term "comprising"

encompass structures which is not part of SEQ ID NO:2. Claimed antibody which bind protein variants encompass a large genus of antibodies which bind proteins or channels which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

10. Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompass an antibody which binds HSATU68 polypeptide variants and fragments which is an orphan G-protein receptor. However, the specification does not teach how to use an antibody which binds peptide variant or fragment HSATU68 polypeptide because HSATU68 polypeptide has no ligand which can be used to determine a function for the HSATU68 polypeptide protein. Although the specification provides examples of making the HSATU68 polypeptide using recombinant methods, without a functional activity of a HSATU68 polypeptide one skilled in the art cannot use the HSATU68 polypeptide. No working example is provided to use a functional HSATU68 polypeptide because the ligand for the HSATU68 polypeptide is not known

without which the function of the protein is unknown. One skilled in the art could not use a functional HSATU68 polypeptide when the ligand is not known. Without such disclosures, the quantity of experimentation necessary to determine the function of HSATU68 polypeptide is extremely large and unpredictable. The specification provides for screening for antagonist and agonist of the HSATU68 polypeptide, but without a functional activity of a HSATU68 polypeptide one skilled in the art cannot use the HSATU68 polypeptide. Without a working example of how to use a functional assay, one skilled in the art could not predict which agonist or antagonist would interact with HSATU68 polypeptide. The number of experimentation is unpredictable because a random screening without a function would be meaningless. Since it is unpredictable whether an agonist or an antagonist could be found, the process of using the agonist or antagonist is unpredictable as well. Non-naturally occurring synthetic, isolated and /or recombinant HSATU68 polypeptide which are fragments, consensus fragments and/or sequences having conservative amino acid substitutions of at least one transmembrane domain of the HSATU68 polypeptide cannot be used without a functional ligand which binds HSATU68 polypeptide. Furthermore, G-protein binding receptors have binding domain comprising the hydrophobic pocket created by all seven of the transmembrane region and even the most conservative nucleotide changes leads to non functional protein or drastically altered binding. The state of the art is such that one skilled in the art cannot use the primary amino acid sequence of HSATU68 polypeptide alone to predict the tertiary structure of HSATU68 polypeptide which would be required to determine ligand binding and function of HSATU68 polypeptide. No working example is

provided to indicate that a hydrophobic ligand binding pocket for HSATU68 polypeptide exist nor whether a change in the hydrophobic ligand binding pocket for HSATU68 polypeptide could bind a ligand that does not exist. The guidance for making antibody for HSATU68 polypeptide is provided but the use of antibodies to HSATU68 polypeptide requires undue experimentation since the function of HSATU68 polypeptide is not known. Any use of antibody of HSATU68 polypeptide could not be used for diagnostic assays since the disease or function drawn to HSATU68 polypeptide is not known. One skilled in the art could not predict what disease state is mediated by HSATU68 polypeptide. The guidance for using polynucleotide hybridization probes of HSATU68 polypeptide are provided but is unpredictable that any DNA that encodes a functional HSATU68 polypeptide could be isolated. Since the HSATU68 polypeptide protein has no function the DNA encoding HSATU68 polypeptide cannot use the HSATU68 polypeptide. The hybridization to detect HSATU68 polypeptide polynucleotides for diagnostic assay could not be used since the disease or function mediated by HSATU68 polypeptide is not known. It is unpredictable and require undue experimentation to determine the a disease or function mediated by HSATU68 polypeptide without a functional ligand. Even with the a known functional ligand for HSATU68 polypeptide, the disease mediated by HSATU68 polypeptide must be determined. Thus, it is unpredictable for one skilled in the art to use the nucleic acid molecules encoding HSATU68 polypeptide polypeptides and would require undue experimentation. In view of the extent and the unpredictability of the experimentation

required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak
Michael Pak
Primary Patent Examiner
Art Unit 1646
18 July 2003